IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

MORTON GROVE PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	No. 08-CV-1384
vs.	)	Judge Bucklo Magistrate Judge Mason
THE NATIONAL PEDICULOSIS ASSOCIATION, INC.,	)	**JURY TRIAL DEMANDED**
Defendant.	)	

THE NATIONAL PEDICULOSIS ASSOCIATION, INC.'S OPPOSITION TO PLAINTIFF'S MOTION TO STRIKE ALLEGATIONS AND DEFENSES IN DEFENDANT'S ANSWER AND COUNTERCLAIM

INTRODUCTION

Courts strongly disfavor motions to strike because they usually delay resolution of the matter and waste judicial resources. The motion filed by Morton Grove Pharmaceuticals, Inc. ("Morton Grove") is a textbook case. In its counterclaim, the National Pediculosis Association, Inc. ("NPA") alleges that, in response to certain actions by the U.S. Food and Drug Administration ("FDA") highlighting the dangers of Morton Grove's lindane products, Morton Grove embarked on a marketing campaign of false and misleading promotional claims in violation of the Lanham Act. NPA further alleges that Morton Grove has continued to make these claims even after the FDA informed it that similar claims it made elsewhere were misleading. By its motion, Morton Grove seeks to strike references to the FDA's actions in NPA's counterclaim. These allegations, however, are essential context for understanding Morton Grove's marketing campaign of its products -- as demonstrated by Morton Grove's inclusion of them in its complaint against NPA, and NPA's reliance on them in answering that

complaint. Because Morton Grove has failed to show that these allegations are immaterial or scandalous, the Court should deny Morton Grove's motion to strike.

ARGUMENT

I. MOTIONS TO STRIKE ARE DISFAVORED AND SHOULD BE DENIED UNLESS THE MOVANT CAN SATISFY A VERY SIGNIFICANT BURDEN.

"Motions to strike under [Federal] Rule [of Civil Procedure] 12(f) are disfavored and usually denied." *Spencer v. Dawson*, No. 04 C 5048, 2005 WL 643331, at *6 (N.D. Ill. Mar. 3, 2005) (citation omitted) (App. 1).[1] Accordingly, courts have held that motions to strike "will only be granted where the allegations have 'no relation to the controversy and [are] unduly prejudicial.'" *Extra Equipamentos E Exportacao Ltda. v. Case Corp.*, No. 01 C 8591, 2005 WL 843297, at *13 (N.D. Ill. Jan. 20, 2005) (quotation omitted) (alteration in original) (App. 2). Furthermore, "[t]he burden to meet the above strong showing is on the movant, who must specifically explain why the paragraphs are repetitive, immaterial or scandalous. Even if such a showing is made, however, the motion should be denied if 'the allegations might serve to achieve a better understanding of the claim . . . or perform some other useful purpose in the just disposition of the litigation.'" *Id.* (citation and quotation omitted) (alteration in original).

Morton Grove has moved to strike allegations in NPA's counterclaim about the black box warning on its lindane products and allegations about a warning letter sent to Morton Grove by the FDA detailing additional false and misleading advertisements Morton Grove used for these same products (collectively, the "FDA allegations"). Morton Grove does not contend that the FDA allegations are untrue or that NPA has exaggerated or mischaracterized the events they describe. Quite the opposite -- Morton Grove acknowledges that these allegations describe "the FDA performing its proper functions." (MG Mem. at 7.) Rather, Morton Grove asserts that

[1] Citations to "App." refer to the appendix of unpublished cases that accompanies this memorandum. Citations to "Ex." refer to the exhibits that are attached to this memorandum.

NPA included the FDA allegations "to detract from the claims and defenses at issue and throw mud at Morton Grove." (*Id.*) This assertion is wrong; the FDA allegations are highly relevant to the issues to be decided in this matter. Morton Grove has not met its high burden, and, therefore, its motion should be denied.

II. MORTON GROVE CANNOT SHOW THAT NPA'S ALLEGATIONS ARE REPETITIVE, IMMATERIAL OR SCANDALOUS.

A. The FDA Allegations Are Highly Relevant.

This litigation is primarily about whether NPA and Morton Grove properly inform the public about the potential risks and dangers associated with lindane, the active ingredient in Morton Grove's products. The FDA's actions are integral to understanding that issue. At issue are: (1) lindane's safety; and (2) the marketing of products containing lindane. The actions taken by the FDA and detailed in the FDA allegations are key to understanding both.

1. The FDA allegations are relevant to the material issues in this case.

As demonstrated by Morton Grove's complaint, neither party can accurately tell the story of Morton Grove's lindane products without discussing the FDA's role. In paragraph 9 of its complaint, Morton Grove alleges that: "in 2003, important advancements to the packaging and prescription of Lindane medications manufactured and sold in the United States served to mitigate the potential risks associated with product misuse and further enhanced their public safety." (Dkt. No. 1, Compl. ¶ 9.) The new labeling alleged in paragraph 9 of Morton Grove's complaint is the same FDA action referred to in the allegations concerning the black box warning that Morton Grove now wants stricken from the counterclaim. (*See* Ex. 1, FDA Talk Paper; Ex. 2, FDA Public Health Advisory; Ex. 3, A Guide to Drug Safety Terms at FDA, at 1.) Morton Grove simply chose not to refer to the new labeling requirement as a black box -- even though that is what the FDA calls it. (*See id.*)

Furthermore, NPA's answer to paragraph 9 of Morton Grove's complaint explains in detail the new black box labeling required as part of the public health warning issued by the FDA in 2003. (Dkt. No. 30, Ans. ¶ 9.) NPA's answer to paragraph 9 (as well as to paragraphs 5, 6, and 20) of Morton Grove's complaint is virtually identical to the allegations contained in paragraphs 20-24, 75, 81, 87 and 94 of NPA's counterclaim that Morton Grove seeks to strike as immaterial. Yet Morton Grove does not seek to strike these allegations from NPA's answer.

Moreover, Morton Grove concedes the relevance of the FDA's actions by referring to the FDA numerous times in its complaint as part of its claim that NPA made false statements about Morton Grove's products. In paragraph 24, Morton Grove specifically refers to the FDA's function of regulating the labeling of Morton Grove's products. (Dkt. No. 1, Compl. ¶ 24.) Morton Grove further alleges that NPA's purported advertising campaign "blatantly ignores all standards for comparative marketing, including those promulgated by the FDA's Division of Drug Marketing and Advertising" and then cites to the Federal Food, Drug and Cosmetic Act. (*Id.* ¶ 22.) Morton Grove also refers to various actions taken by the FDA in six more paragraphs of its complaint. (*Id.* ¶¶ 1, 5, 6, 20, 37 & 42.)

2. The FDA allegations are relevant to NPA's counterclaim.

The FDA allegations are material to the issues raised in NPA's counterclaim. The basic premise of the counterclaim is that Morton Grove made misleading statements by downplaying the risks of its own products in order to encourage doctors to prescribe and consumers to use its lindane products. The FDA allegations are relevant, at a minimum, to explain the context in which Morton Grove made its misleading statements. They detail how, over the past 15 years, in light of the toxicity and other dangers associated with lindane, the FDA and other government entities have imposed increasingly stringent restrictions on packaging, labeling and approved uses of Morton Grove's products. These regulatory restrictions, which have drawn attention to

the serious risks associated with the use of lindane products, are at least part of the reason Morton Grove has sought, through its advertising, to downplay these risks and to discredit NPA and other non-profit organizations that warn about the dangers of the chemical lindane and its use in pharmaceutical products. In other words, the FDA allegations are all or part of the reason Morton Grove made its misleading statements and thus provide relevant context to NPA's counterclaim. Also, as is evident from its own complaint, Morton Grove undoubtedly will rely on other actions taken by the FDA to support its defense that the statements it made are not misleading. (*See, e.g.*, Dkt. No. 1, Compl. ¶¶ 5, 6, 20 & 24.)

The *Noerr-Pennington* doctrine also does not make the FDA allegations irrelevant. *Duramed Pharmaceuticals, Inc. v. Wyeth-Ayerst Laboratories, Inc.*, No. C-1-00-735, slip op. (S.D. Ohio Aug. 1, 2001) (App. 3), upon which Morton Grove relies, is readily distinguishable. (MG Mem. at 8.) In *Duramed*, the court held, and Duramed admitted, that Duramed could not base its antitrust claim on any statements Wyeth made to the FDA about Duramed's product because such statements, involving direct petitioning to the government for action, are protected under the *Noerr-Pennington* doctrine. *Id.* at 7. As such, the court struck those allegations. *Id.* at 12.

Here, by contrast, Morton Grove wants to strike statements made by the FDA to Morton Grove about Morton Grove's products, not statements Morton Grove made to the FDA. As explained more fully in NPA's opposition to Morton Grove's motion to dismiss filed contemporaneously with this opposition, the *Noerr-Pennington* doctrine only applies to statements made to the government, not vice versa. *See, e.g.*, *MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1159-60 (7th Cir. 1983). Furthermore, the law is clear that a party can maintain a Lanham Act claim for false advertising even if the product advertised is regulated

by the FDA. *See, e.g.*, *Genderm Corp. v. Biozone Labs.*, No. 92 C 2533, 1992 WL 220638, at *2 (N.D. Ill. Sept. 3, 1992) (App. 4) (holding that even though FDA had exclusive jurisdiction over approval of product and interpretation of whether FDA monograph applied to certain chemical, court could still determine if defendant made false statements under the Lanham Act concerning that product); *Ehrhart v. Synthes*, No. 07-01237, 2007 WL 4591276, at *6 (D.N.J. Dec. 28, 2007) (App. 5) (denying motion to strike allegations concerning fraud on the FDA even though such claims are preempted because plaintiff's claim was not based solely on a violation of the FDA requirements).

NPA's counterclaim turns on the false and misleading nature of Morton Grove's claims about the safety and efficacy of its products, and Morton Grove has implicitly acknowledged that the FDA's actions are important to understanding that issue by including allegations about FDA in its own complaint. Therefore, Morton Grove has not met, and cannot meet, its heavy burden of establishing that these allegations in the counterclaim are immaterial or impertinent.

B. The FDA Allegations Are Not Scandalous Simply Because They Are Unflattering to Morton Grove.

Morton Grove argues that the FDA allegations are scandalous because they cast Morton Grove and its products in a derogatory light. It then curiously argues that the FDA allegations concern matters that are "routine in the pharmaceutical industry." (MG Mem. at 9.) If such FDA actions are indeed routine, it is unclear how allegations about these actions are improperly derogatory. Furthermore, at trial, Morton Grove will be free to argue its position concerning the meaning and importance of these actions taken by the FDA. The FDA allegations describe NPA's "view of the events . . . . The fact that this view is unflattering" to Morton Grove "is not a valid reason" to grant the motion to strike "as allegations in a complaint cannot be stricken

merely because [the other party] disagrees with them." *Spencer*, 2005 WL 643331, at *6 (citation omitted) (App. 1).

Moreover, *Talbot v. Robert Matthews Distributing Co.*, 961 F.2d 654 (7th Cir. 1992), which Morton Grove cites to support its argument (MG Mem. at 9), is inapposite. In *Talbot*, the Seventh Circuit held that the district court did not abuse its discretion by striking allegations that the defendants intentionally caused a salmonella outbreak that resulted in deaths because the allegations were "devoid of any factual basis." 961 F.2d at 665. Morton Grove does not -- and cannot -- argue that the FDA allegations are devoid of any factual basis. There is no question that the FDA took the actions set forth in the FDA allegations. Again, Morton Grove has utterly failed to meet its burden of establishing that the FDA allegations should be stricken as scandalous.

C. The FDA Allegations Do Not Unduly Prejudice Morton Grove.

Morton Grove's argument that the FDA allegations are unduly prejudicial to it fares no better. Morton Grove claims that the FDA allegations will "confuse the issues," that the warning letter casts it "in a negative light," that the black box warnings "make its products look harmful" and will somehow "prejudice the public," that NPA "insinuates that Morton Grove acted improperly" and that the Court will have to "conduct a mini-trial" on these issues. (MG Mem. at 11-12.) It utterly fails, however, to show any undue prejudice from the FDA allegations.

First, far from confusing the issues in this matter, the FDA warning letter provides useful context for NPA's claims. Morton Grove argues that the warning was only "the beginning of a dialogue" with the FDA and that repeatedly mentioning the letter casts it in a negative light "as if the FDA was taking some final disciplinary action against" it. (MG Mem. at 10-11.) Morton Grove will be free to argue its interpretation and importance of the warning letter as this case progresses. The fact is the FDA states in the warning letter that Morton Grove's advertisements

-- which are very similar to the ones at issue in the counterclaim -- are false or misleading because they downplay the risks associated with its products.

Second, there is nothing "undue" about an inference that Morton Grove's products have a black box because they are potentially harmful. Morton Grove argues that NPA included its allegations about the black box warnings "as a way to discredit Morton Grove and make its products look harmful." (MG Mem. at 11.) The whole issue here is whether Morton Grove downplayed the significant safety risks associated with the key active ingredient in its lindane products in violation of the Lanham Act. The finder of fact will need to know those risks in order to make that evaluation. As the FDA explained, the labeling of Morton Grove's products was "changed to include a boxed warning which highlights the most important safety issues associated with use of these products. . . . Given the possible risks associated with the use of [Morton Grove's products], healthcare providers should consider this new safety information when deciding whether to prescribe" those products for patients who may be at risk. (Ex. 1, FDA Talk Paper at 1-2.)

NPA asserts in its counterclaim that Morton Grove misleadingly downplayed these risks in materials Morton Grove sent to doctors and posted on its websites, which are accessible to doctors and consumers. That the FDA has required a black box on lindane products supports the seriousness of these risks, and the black box warning itself explains some of these risks. To the extent Morton Grove's objection is to NPA's use of the term "black box," NPA's choice of this common term for the boxed warning is not sufficient to make the FDA allegations unduly prejudicial. *See Ace Hardware Corp. v. Marn, Inc.*, No. 06 C5335, 2006 WL 4007863, at *2 (N.D. Ill. Dec. 27, 2006) (App. 6) (denying motion to strike plaintiff's use of term *modus operandi* despite defendants' argument that term is used to denote criminal conduct, holding that

use of term "does not confuse the issues nor does it place undue burden on Defendants' ability to respond to Complaint").

Third, Morton Grove's odd argument that the FDA allegations improperly prejudice it to the public (which is not even the standard on a motion to strike) simply because they are included in a public court document makes no sense. (MG Mem. at 11.) The FDA Public Health Advisory and related materials concerning the black box and the warning letter are all easily accessible on the FDA's public website.

Fourth, Morton Grove's argument that NPA's counterclaim "insinuates that Morton Grove acted improperly and perhaps criminally" is not a basis for striking allegations. (MG Mem. at 11.) The counterclaim does allege that Morton Grove acted improperly in violation of the Lanham Act, but that is nothing more than what Federal Rule of Civil Procedure 8 requires; it would be an odd complaint that did not allege the defendant acted improperly and in violation of the law. Furthermore, there is no suggestion of any criminal conduct in the allegations Morton Grove seeks to strike or elsewhere in the counterclaim.

Finally, Morton Grove's claim that the FDA allegations will require the Court to "conduct a mini-trial within the trial on the collateral issue of the product's FDA-approved labeling and Morton Grove's regulatory relationship with the FDA" is baseless. (MG Mem. at 12.) The FDA allegations are facts, like other relevant facts, that the trier of fact will consider. If anything, these facts will take less time at trial than other facts because the parties do not dispute what happened. In any event, Morton Grove already has put these facts at issue by making allegations in its complaint about "improved labeling" and other actions it took at the direction of the FDA so striking the FDA allegations from the counterclaim will not make a "mini-trial" any less likely.

Morton Grove has not even come close to demonstrating that it will be unduly prejudiced by the inclusion of the FDA allegations in the counterclaim, especially given that Morton Grove opened the door by affirmatively raising the FDA's actions in its complaint. While Morton Grove may not want the jury to hear about the serious actions the FDA has taken in light of the risks associated with the key ingredient in Morton Grove's products, that is not a sufficient reason for striking them. The Court should not let Morton Grove cherry-pick which FDA actions it views as beneficial while excluding those that it does not like but are relevant to the issues to be decided.

D. NPA's Affirmative Defenses.

Morton Grove makes a number of arguments as to why all of NPA's defenses should be stricken. NPA disagrees and believes that Morton Grove is fully apprised of the bases of NPA's defenses given its motion to dismiss and its interrogatory responses. Nevertheless, to resolve this issue, NPA is prepared to file amended affirmative defenses, a copy which is attached hereto as Exhibit 4. NPA has removed its non-affirmative defenses from its answer and has pled additional factual allegations to support its affirmative defenses.[2] NPA requests that the Court grant it leave to file its amended affirmative defenses.

CONCLUSION

Morton Grove has utterly failed to demonstrate that the FDA allegations in NPA's counterclaim are immaterial, scandalous or unduly prejudicial. To the contrary, Morton Grove's

[2] By removing its non-affirmative defenses, NPA does not in any way concede that Morton Grove is correct that the Court already has ruled on these defenses, and, therefore, NPA is precluded from raising them on summary judgment. A review of the opinion issued by the Court in connection with NPA's motion to dismiss Morton Grove's complaint in the prior action (attached as Ex. A to Morton Grove's motion to strike) demonstrates that the Court did no such thing. The Court simply held that taking all of the allegations in Morton Grove's complaint as true, certain claims were sufficient to withstand the motion to dismiss. The Court did not even address some of the defenses raised by NPA in its motion.

own complaint and NPA's answer thereto demonstrate that these issues are central to the claims in this case. Moreover, Morton Grove should not be permitted to selectively rely on those FDA actions it views as beneficial to its litigation while preventing NPA from putting those actions in proper context.

Dated: July 24, 2008

Respectfully Submitted,

THE NATIONAL PEDICULOSIS ASSOCIATION, INC.

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CERTIFICATE OF SERVICE

I, Debbie L. Berman, hereby certify that on July 24, 2008, I caused copies of the foregoing **Defendant The National Pediculosis Association, Inc.'s Opposition to Plaintiff's Motion to Strike Allegations and Defenses in Defendant's Answer and Counterclaim,** to be served upon the following via electronic filing through the CM/ECF system:

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